SELF-ADMINISTERED DRUG(S) (SAD)

Guideline Number: MPG280.03

Approval Date: October 11, 2017

Table of Contents

<table>
<thead>
<tr>
<th>TERMS AND CONDITIONS</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>PURPOSE</td>
<td>1</td>
</tr>
<tr>
<td>POLICY SUMMARY</td>
<td>2</td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>3</td>
</tr>
<tr>
<td>DEFINITIONS</td>
<td>4</td>
</tr>
<tr>
<td>QUESTIONS AND ANSWERS</td>
<td>5</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>5</td>
</tr>
</tbody>
</table>

GUIDELINE HISTORY/REVISION INFORMATION: 8

TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT® **), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

**CPT® is a registered trademark of the American Medical Association.

PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.
UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

### POLICY SUMMARY

#### Overview

The Centers for Medicare and Medicaid Services (CMS) publishes guidelines instructing contractors to develop a process to determine whether a drug or biological is usually self-administered and excluded from payment. The program covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually administered by the patients who take them. Generally, drugs and biologicals are covered only if all of the following requirements are met:

- They meet the definition of drugs or biologicals
- They are of the type that are not usually self-administered
- They meet all the general requirements for coverage of items as incident to a physician's service
- They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administering according to accepted standards of medical practice
- They are not excluded as Noncovered immunizations
- They have not been determined by the FDA to be less than effective

Medicare Part B generally does not cover drugs that can be self-administered, such as those in pill form, or are used for self-injection. However, the statute provides for the coverage of some self-administered drugs. Examples of self-administered drugs that are covered include blood-clotting factors, drugs used in immunosuppressive therapy, erythropoietin for dialysis patients, osteoporosis drugs for certain homebound patients, and certain oral cancer drugs.

#### Guidelines

We are instructed to follow the instructions below when applying the exclusion for drugs that are usually self-administered by the patient. Each individual contractor must make its own individual determination on each drug. Contractors must continue to apply the policy that not only the drug is medically reasonable and necessary for any individual claim, but also that the route of administration is medically reasonable and necessary. If a drug is available in both oral and injectable form, the injectable form of the drug must be medically reasonable and necessary as compared to using the oral form.

For certain injectable drugs, it is apparent that due to the nature of the condition(s) for which they are self-administered or the usual course of treatment for those conditions, they are, or are NOT, usually self-administered. For example, an injectable drug used to treat migraine headaches is usually self-administered. For these drugs, the rationale for the determination is "apparent on its face value."

The following factors are considered when making decisions regarding the "self-administered" status of a drug when data is not available.

#### Route of Administration

- Drugs delivered intravenously are presumed to be not usually self-administered
- Drugs injected intramuscularly are presumed to be not usually self-administered, although depth and nature of the drug may be considered
- Drugs delivered subcutaneously are considered to be usually self-administered
- Drugs delivered by other routes of administration such as oral, suppositories, and topical medications are all considered to be usually self-administered

#### Status of Condition

- Acute: Any condition that the expected course of treatment is less than two weeks
- Chronic: Any condition that requires treatment for more than two weeks

#### Frequency of Administration

- Infrequent Injection: Drug given monthly or less than once a month
- Frequent Injection: Drug given one or more times per week or more than once per month

The term “administered” refers only to the physical process by which the drug enters the patient’s body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or
side-effects of the drug). Injectable (including intravenous) drugs are typically eligible for inclusion under the “incident to” benefit. With limited exceptions, other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are all considered to be usually self-administered by the patient.

For the purpose of applying this exclusion, the term “usually” means more than 50% of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50% of Medicare beneficiaries, the drug is excluded from coverage and the contractor may not make any Medicare payment for it. Contractors are further instructed to make this determination on a drug-by-drug basis, not on a beneficiary-by-beneficiary basis.

In arriving at a single determination as to whether a drug is usually self-administered, contractors should make a separate determination for each indication for a drug as to whether that drug is usually self-administered. **Contractors may no longer pay for any drug when it is administered on an outpatient emergency basis, if the drug is excluded because it is usually self-administered by the patient.**

Contractors are only required to consider the following types of evidence:

- Peer reviewed medical literature
- Standards of medical practice
- Evidence-based practice guidelines
- FDA approved label
- Package inserts
- Drug compendia references
- Self-administration utilization statistics

Contractors may also consider other evidence submitted by interested individuals or groups subject to their judgment.

**Self-Administered Drug Process Flow**

The process steps to determine whether a drug is self-administered are as follows:

- Determine if the drug is produced in parenteral form
- Determine the route of administration – if only administered IV, the drug is covered
- Determine if the route of administration is IM or SQ, and if the drug is administered in the outpatient setting, list the clinical indications and determine the percent of utilization by clinical indication
- Review claims data and check a variety of sources/factors to arrive at the preliminary recommendation:
  - Acute/chronic setting
  - Clinical indication
  - FDA/drug package inserts
  - Provider specialty
  - Estimate the % self-administered (greater than or less than 50%) by indication
  - Assess all information to determine whether the drug is covered under the benefit category and notify providers.

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

**CPT/HCPCS Codes**

<table>
<thead>
<tr>
<th>Revenue Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0637</td>
<td>Self-administered drugs (Use this revenue code for self-administered drugs not requiring detailed coding)</td>
</tr>
</tbody>
</table>

**Coding Clarifications:**

- Value Codes (FLs 39-41), A4, A5 and A6 are used to report the dollar amount included in covered charges for self-administered drugs. Amounts for Noncovered charges should be reflected in the Noncovered charge column (FL 48) aligned with this revenue code.
• The self-administered drug Insulin, administered in an emergency situation to a patient in a diabetic coma, should be billed using this revenue code.
  o Also, report the appropriate TOB code (FL 4) 013x or 085x.
  o Enter Value code A4 and its related dollar amount in FLs 39-41. This should be the amount included in covered charges (FL 47) for the ordinarily noncovered, self-administrable drug, Insulin.
  o The costs of inpatient self-administrable drugs are included in the inpatient MS-DRG payment and should not be billed to the patient.
• For all providers, each line item billed as not covered must be identified with a HCPCS code and associated modifier. This includes all OPPS packaged items and those items traditionally not billed with HCPCS codes in the past.
  o Report the most specific HCPCS code available to describe the item or service.
  o If no specific HCPCS code exists, report HCPCS code A9270 Noncovered item or service. All providers may report this code when applicable.
  o HCPCS code A9270 code is by definition, not covered and the item will be immediately denied. The Provider will be held liable for items or services billed with HCPCS code A9270 unless an organizational predetermination notification is received.
• If revenue code 0637 is reported on an outpatient claim without a HCPCS code, it will be processed as a non-covered service when no HCPCS codes are present.

DEFINITIONS

Acute Condition: Any condition that the expected course of treatment is less than two weeks (drug for this indication is considered “not usually self-administered”).

"Apparent on its Face": For certain injectable drugs, it will be apparent due to the nature of the condition(s) for which they are administered or the usual course of treatment for those conditions, they are, or are not, usually self-administered. On the other hand, an injectable drug, administered at the same time as chemotherapy, used to treat anemia secondary to chemotherapy is not usually self-administered.

Chronic Condition: Any condition that requires treatment for more than two weeks (drug for this indication is considered “usually self-administered by the patient”).

Drugs and Biologicals: Must be determined to meet the statutory definition. Under the statute §1861(t)(1), payment may be made for a drug or biological only where it is included, or approved for inclusion, in the latest official edition of the United States Pharmacopoeia National Formulary (USP-NF), the United States Pharmacopoeia-Drug Information (USD-DI), or the American Dental Association (ADA) Guide to Dental Therapeutics, except for those drugs and biologicals unfavorably evaluated in the ADA Guide to Dental Therapeutics. The inclusion of an item in the USP DI does not necessarily mean that the item is a drug or biological. The USP DI is a database of drug information developed by the U.S. Pharmacopoeia but maintained by Micromedex, which contains medically accepted uses for generic and brand name drug products. Inclusion in such reference (or approval by a hospital committee) is a necessary condition for a product to be considered a drug or biological under the Medicare program, however, it is not enough. Rather, the product must also meet all other program requirements to be determined to be a drug or biological. Drugs and biologicals are considered approved for inclusion in a compendium if approved under the established procedure by the professional organization responsible for revision of the compendium.

Off-Label Drug Use: An off-label/unlabeled use of a drug is defined as a use for a non-FDA approved indication, that is, one that is not listed on the drug's official label/prescribing information. An indication is defined as a diagnosis, illness, injury, syndrome, condition, or other clinical parameter for which a drug may be given. Off-label use is further defined as giving the drug in a way that deviates significantly from the labeled prescribing information for a particular indication. This includes but is not necessarily limited to, dosage, route of administration, duration and frequency of administration, and population to whom the drug would be administered. Drugs used for indications other than those in the approved labeling may be covered under Medicare if it is determined that the use is medically accepted, taking into consideration the major drug compendia, authoritative medical literatures and/or accepted standards of medical practice. Determinations as to whether medication is reasonable and necessary for an individual patient are made on appeal on the same basis as all other such determinations (i.e., with support from the peer-reviewed literature, with the advice of medical consultants, with reference to accepted standards of medical practice, and in consideration of the medical circumstance of the individual case).

Self-Administered By the Patient: The term “by the patient” means Medicare beneficiaries as a collective whole. The contractor includes only the patients themselves and not other individuals (that is, spouses, friends, or other caregivers are not considered the patient). The determination is based on whether the drug is self-administered by the patient a majority of the time that the drug is used on an outpatient basis by Medicare beneficiaries for medically necessary indications. The contractor ignores all instances when the drug is administered on an inpatient basis.
**Usually Self-Administered:** If a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage. In arriving at a single determination as to whether a drug is usually self-administered, contractors should make a separate determination for each indication for a drug as to whether that drug is usually self-administered. After determining whether a drug is usually self-administered for each indication, contractors should determine the relative contribution of each indication to total use of the drug (i.e., weighted average) in order to make an overall determination as to whether the drug is usually self-administered. For example, if a drug has three indications, is not self-administered for the first indication, but is self-administered for the second and third indications, and the first indication makes up 40 percent of total usage, the second indication makes up 30 percent of total usage, and the third indication makes up 30 percent of total usage, then the drug would be considered usually self-administered.

**QUESTIONS AND ANSWERS**

<table>
<thead>
<tr>
<th>Q:</th>
<th>What if a beneficiary wants to appeal the denial of a self-administered drug?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A:</td>
<td>If a beneficiary’s claim for a particular drug is denied because the drug is subject to the “self-administered drug” exclusion, the beneficiary may appeal the denial. Because it is a “benefit category” denial and not a denial based on medical necessity, an advance notification of denial is not required. A “benefit category” denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability (under §1879 of the Act). Therefore, physicians or providers may charge the beneficiary for an excluded drug.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Q:</th>
<th>How often will M&amp;R review the list of self-administered drugs?</th>
</tr>
</thead>
<tbody>
<tr>
<td>A:</td>
<td>CMS expects that review of injectable drugs will be performed on a rolling basis and no less frequently than annually.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Q:</th>
<th>What does “incident to” mean?</th>
</tr>
</thead>
</table>
| A: | In order to meet all the general requirements for coverage under the incident-to provision, an FDA approved drug or biological must:  
  - Be of a form that is not usually self-administered  
  - Must be furnished by a physician  
  - Must be administered by a physician, or by auxiliary personnel employed by the physician and under the physician’s personal supervision  
  - The charge must be included in the Physician’s bill AND  
  - The cost of the drug or biological must represent an expense to the physician |

**REFERENCES**

**CMS Articles**

<table>
<thead>
<tr>
<th>Article</th>
<th>HHH MAC</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
</tr>
</thead>
<tbody>
<tr>
<td>A53894 (Self-Administered Drugs - Process to Determine Which Drugs Are Not Usually Self-administered By the Patient) Noridian</td>
<td>AS, CA, GU, HI, MP, NV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A53893 (Self-Administered Drugs - Process to Determine Which Drugs Are Not Usually Self-administered By the Patient) Noridian</td>
<td>AS, CA, GU, HI, MP, NV</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A53034 (Self-Administered Drugs - Process To Determine Which Drugs Are Usually Self-Administered by the Patient) Noridian</td>
<td>AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY</td>
<td>AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY</td>
<td></td>
</tr>
<tr>
<td>A52527 (Self-Administered Drug Exclusion List and Biologicals Excluded from Coverage - Medical Policy Article (R7)) CGS</td>
<td>CO, DC, DE, IA, KS, MD, MO, MT, ND, NE, PA, SD, UT, VA, WV, WY</td>
<td>KY, OH</td>
<td>KY, OH</td>
</tr>
<tr>
<td>Article</td>
<td>HHH MAC</td>
<td>Medicare Part A</td>
<td>Medicare Part B</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>A52800 (Self-Administered Drug Exclusion List (SAD List)) WPS</td>
<td>AK, AL, AR, AZ, CT, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, OH, OR, RI, SC, SD, TN, UT, VA, VI, VT, WA, WI, WV, WY</td>
<td>IA, KS, MO, NE, IN, MI</td>
<td></td>
</tr>
<tr>
<td>A52571 (Self-Administered Drug Exclusion List - Medicare Payment for Drugs and Biologicals Furnished Incident to a Physician’s Service) First Coast</td>
<td>FL, PR, VI</td>
<td>FL, PR, VI</td>
<td></td>
</tr>
<tr>
<td>A53022 (Self-Administered Drug Exclusion List - Medical Policy Article) NGS</td>
<td>IL, MN, WI</td>
<td>IL, MN, WI</td>
<td></td>
</tr>
<tr>
<td>A53021 (Self-Administered Drug Exclusion List - Medical Policy Article) NGS</td>
<td>CT, NY, ME, MA, NH, RI, VT</td>
<td>CT, NY, ME, MA, NH, RI, VT</td>
<td>CT, NY, ME, MA, NH, RI, VT</td>
</tr>
<tr>
<td>A52700 (Self-Administered Drug Exclusion List - JJ MAC) Cahaba</td>
<td>AL, GA, TN</td>
<td>AL, GA, TN</td>
<td></td>
</tr>
<tr>
<td>A53066 (Self-Administered Drug Exclusion List) Palmetto</td>
<td>SC, VA, WV, NC</td>
<td>SC, VA, WV, NC</td>
<td></td>
</tr>
<tr>
<td>A53127 (Self-Administered Drug Exclusion List) Novitas</td>
<td>AR, CO, DC, DE, LA, MD, NM, MS, NJ, OK, PA, TX</td>
<td>AR, CO, DC, DE, LA, MD, NM, MS, NJ, OK, PA, TX</td>
<td></td>
</tr>
<tr>
<td>A53033 (Self-Administered Drug Exclusion List) Noridian</td>
<td>AZ, AK, ID, MT, ND, OR, SD, UT, WA, WY</td>
<td>AZ, AK, ID, MT, ND, OR, SD, UT, WA, WY</td>
<td></td>
</tr>
<tr>
<td>A53032 (Self-Administered Drug Exclusion List) Noridian</td>
<td>AS, CA, GU, HI, MP, NV</td>
<td>AS, CA, GU, HI, MP, NV</td>
<td></td>
</tr>
<tr>
<td>A55019 (Self-administered drug (SAD) list revision to the Part A and Part B article: asfotase alfa (Strensiq™) J3490/J3590/C9399) First Coast</td>
<td>FL, PR, VI</td>
<td>FL, PR, VI</td>
<td></td>
</tr>
<tr>
<td>A54770 (Self-administered drug (SAD) list Praluent® (alirocumab), repatha™ (evolocumab), and natpara® (parathyroid hormone) J3490/J3590/C9399) First Coast</td>
<td>FL, PR, VI</td>
<td>FL, PR, VI</td>
<td></td>
</tr>
<tr>
<td>A53020 (Process for Determining Self-Administered Drug Exclusions – Medical Policy Article) NGS</td>
<td>CT, MA, ME, NH, NY, RI, VT</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI,</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI,</td>
</tr>
<tr>
<td>A52535 (Process for Determining Self-Administered Drug Exclusions – Medical Policy Article) CGS</td>
<td>KY, OH</td>
<td>KY, OH</td>
<td></td>
</tr>
<tr>
<td>A52884 (Changes in Noridian’s List of Drugs that are Usually Self-Administered) Noridian</td>
<td></td>
<td>AZ, AK, ID, MT, ND, OR, SD, UT, WA, WY</td>
<td></td>
</tr>
<tr>
<td>Article</td>
<td>HHH MAC</td>
<td>Medicare Part A</td>
<td>Medicare Part B</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------</td>
<td>---------</td>
<td>-----------------</td>
<td>-----------------</td>
</tr>
<tr>
<td>A52880 (Changes in Noridian’s List of Drugs that are Usually Self-Administered) Noridian</td>
<td></td>
<td>AS, CA, GU, HI, MP, NV</td>
<td></td>
</tr>
<tr>
<td>A52890 (Changes in Noridian’s List of Drugs that are Usually Self-Administered) Noridian</td>
<td></td>
<td>AS, CA, GU, HI, MP, NV</td>
<td></td>
</tr>
<tr>
<td>A55330 (Self-Administered drug (SAD) list revision to the Part A and Part B article) First Coast</td>
<td></td>
<td>FL, PR, VI</td>
<td>FL, PR, VI</td>
</tr>
</tbody>
</table>

**CMS Benefit Policy Manual**
Chapter 15; § 50 Drugs and Biologicals, § 50.2 Determining Self-Administration of Drug or Biological, §50.3 Incident to Requirements

**CMS Claims Processing Manual**
Chapter 17; § 80.5 Self-Administered Drugs

**CMS Transmittals**
Transmittal 123, Change Request 6950, Dated 04/30/2010 (Determining Self-Administration of Drug or Biological)

**Medicare Advantage Policy Guidelines**
Anti-Cancer Chemotherapy for Colorectal Cancer (NCD 110.17)
Anti-Inhibitor Coagulant Complex (AICC) (NCD 110.3)
Avastin® (Bevacizumab)
Blood-Derived Products for Chronic Non-Healing Wounds (NCD 270.3)
Camptosar® (Irinotecan)
Coverage of Drugs and Biologicals for Label and Off-Label Uses
Diagnosis and Treatment of Impotence (NCD 230.4)
Eloxatin® (Oxaliplatin)
Erbitux® (Cetuximab)
Eylea® (Aflibercept)
Halaven® (Eribulin Mesylate)
Hemophilia Clotting Factors
Home Health Visit to a Blind Diabetic (NCD 290.1)
Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management (NCD 190.11)
Hyperbaric Oxygen Therapy (NCD 20.29)
Infusion Pumps (NCD 280.14)
Insulin Syringe (NCD 40.4)
Interferon
Intravenous Immune Globulin (IVIG)
Intravenous Immune Globulin for the Treatment of Mucocutaneous Blistering Diseases (NCD 250.3)
Jevtana® (Cabazitaxel)
L-Dopa (NCD 160.17)
Lucentis® (Ranibizumab)
Macugen® (Pegaptanib)
Nesiritide for Treatment of Heart Failure Patients (NCD 200.1)
Stem Cell Transplantation (NCD 110.23) (Formerly NCD 110.8.1)
Vaccination (Immunization)
Withdrawal Treatments for Narcotic Addictions (NCD 130.7)
Xgeva®, Prolia® (Denosumab)
Xofigo® Radioactive Therapeutic Agent

**Medicare Advantage Reimbursement Policies**
Discarded Drugs and Biologicals

**Medicare Advantage Coverage Summaries**
Alcohol, Chemical and/or Substance Abuse: Detoxification and Rehabilitation
Blood, Blood Products and Related Procedures and Drugs
Chemotherapy, and Associated Drugs and Treatments
Diabetes Management, Equipment and Supplies
Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid
Home Health Services and Home Health Visits
Infusion Pump Therapy
Medications/Drugs (Outpatient/Part B)
Mental Health Services and Procedures
Preventive Health Services and Procedures
Skin Treatment, Services and Procedures

MLN Matters
Article MM6950, Medicare Benefits Policy Manual Update – Determining Self-Administration of Drug or Biological

Others
Billing for Self-Administered Drugs Given in Outpatient Settings Fact Sheet, CMS Website

Social Security Act:
• 1861(s)(2)(A), Medical and Other Health Service
• 1861(s)(2)(B), Medical and Other Health Service

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/01/2018</td>
<td>• Updated list of related policies to reflect title change for Home Prothrombin</td>
</tr>
<tr>
<td></td>
<td>Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation</td>
</tr>
<tr>
<td></td>
<td>Management (NCD 190.11) (previously titled Home Prothrombin</td>
</tr>
<tr>
<td></td>
<td>Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation</td>
</tr>
<tr>
<td></td>
<td>Treatment (NCD 190.11))</td>
</tr>
<tr>
<td>10/11/2017</td>
<td>• Annual review</td>
</tr>
<tr>
<td></td>
<td>• Revising the attached list of Self-Administered Drugs based on current sources</td>
</tr>
<tr>
<td></td>
<td>• Administrative updates</td>
</tr>
</tbody>
</table>